

**REMARKS**

The Office Action has been carefully reviewed. Claims 23-25 are allowed. Claims 1-4 and 26-28 also presently appear in this application along with new claims 29-37 and define patentable subject matter warranting their allowance.

Reconsideration and allowance are hereby respectfully solicited.

Claims 1-4 and 26-28 have been rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. The examiner holds that there is no enabling support for treating all infections, tumors and autoimmune and inflammatory diseases broadly claimed in the instant invention. The examiner however states that the prior art has disclosed treatment of viral infections including hepatitis B and C, basal cell carcinoma, brain tumor, skin cancer and multiple sclerosis by administering interferon- $\beta$ . This rejection is respectfully traversed.

Claims 1 and 26 are amended to recite for treating viral infections, lupus erythematosus, or rheumatoid arthritis, or for stimulating natural killer cells against neoplastic cells, as supported in the present specification at page 1, lines 17-20 (anti-viral activity and stimulating natural killer cells against neoplastic cells), at page 5, lines 28-29 (no loss of activity with respect to "native" IFN- $\beta$ ) and page 12, lines 7-8 (lupus erythematosus and rheumatoid arthritis). Interferon- $\beta$  is known to treat these recited indications in the prior art. The

examiner has acknowledged that the prior art has disclosed treatment of viral infections including hepatitis B and C (and further supported by the issued claims in U.S. Patent 5,019,382 attached hereto). Attached hereto are references showing that interferon- $\beta$  is known to treat lupus erythamatosus (see attached Tsokos et al., *Clin. Exp. Immunol.* 50:239-245, 1982 reference) and rheumatoid arthritis (see attached letter in *Arthritis Rheum.* 40(7):1370, 1997, and WO 95/27502) in the prior art. Accordingly, the specification and the prior art is enabled for treating the recited indications with interferon- $\beta$  as well as with the polyol-human interferon- $\beta$  conjugate according to the method of the present invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 4 has been rejected under 35 U.S.C. §112, first paragraph, for lack of written description. This rejection is obviated by the amendment to claim 4 to delete the term "native". Thus, amended claim 4 only recites human fibroblast interferon (interferon  $\beta$ ), thereby obviating this rejection.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is also obviated by the amendment to claim 4 to delete the term "native".

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Reconsideration and withdrawal of the rejection are  
therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C.  
§112 and define patentable subject matter warranting their  
allowance. Favorable consideration and early allowance are  
earnestly urged.

Respectfully submitted,

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